



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

FILE COPY

October 20, 2005

Elizabeth Barbehenn, Ph.D.
Peter Lurie, M.D.
Sidney M. Wolfe, M.D.
Howard D. Pomeranz
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, DC 20009-1001

Dear Drs. Barbehenn, Lurie, Wolfe and Pomeranz:

Your petition requesting the Food and Drug Administration to immediately add a black box warning regarding the risks of drug-induced blindness for the three phosphodiesterase 5 inhibitors that are prescribed for the treatment of erectile dysfunction was received by this office on 10/20/2005. It was assigned docket number 2005P-0423/CP1 and it was filed on 10/20/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Gaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2005P-0423

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